UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Subcategory No. 06-11337-PBS
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Dey, Inc., et al., Civil Action No. 05-11084-PBS	)	Hon. Patti B. Saris

UNITED STATES' REPLY IN FURTHER SUPPORT OF CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND SUR-REPLY IN OPPOSITION TO THE DEY DEFENDANTS' MOTION FOR PARTIAL SUMMARY JUDGMENT

TONY WEST
ASSISTANT ATTORNEY GENERAL

MICHAEL K. LOUCKS
ACTING UNITED STATES ATTORNEY

George B. Henderson, II
Assistant U.S. Attorney

Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch

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INTRODUCTION

The Court should schedule this case, and the Roxane case, for trial. None of the parties has moved for summary judgment on all aspects of any case, and, absent settlement, trial appears inevitable. In the meantime, however, the Court's rulings on motions for partial summary judgment will immeasurably clarify and narrow the issues to be tried. Dey's obfuscatory arguments notwithstanding, partial summary judgment as requested by the United States is supported by the undisputed facts and the law. The United States briefly addresses below certain discrete issues argued in Dey's Opposition/Reply brief.

I. DEY'S PRICING DISCLOSURES AND AGENCY KNOWLEDGE DO NOT RAISE LEGALLY SUFFICIENT DEFENSES

Dey continues to assert that its disclosures of average manufacturer prices ("AMPs") and Federal Supply Schedule ("FSS") prices absolve it of liability. Yet, in the case of its AMP data, Dey had no valid reason to believe that such data would ever be used for reimbursement purposes by the Centers for Medicare & Medicaid Services ("CMS"). In addition to CMS's published position regarding the confidentiality of such data, 60 Fed. Reg. 48442 (1995), the Medicaid rebate agreement that Dey signed, and all of the other rebate agreements that Dey has produced in discovery, contain strict confidentiality provisions concerning AMP data. Henderson Common Ex. 30; Reid Ex. 34; Henderson Reply Ex. 92.[1] Dey's observation that four states require drug manufacturers to report AMPs to their Medicaid programs proves nothing. Each of those states

[1] A list of citation abbreviations and their corresponding full citations is appended as an Addendum to this brief.

treats such information in strict confidence.[2] Three of the four states use such information solely for purposes of supplemental rebates, and Maine (which enacted its law in 2003) appears to allow the data to be used to investigate profiteering. Dey concedes that "CMS believed it had to keep the AMPs it received from Dey confidential." Dey Reply Br. at 5.

Nor is it a valid defense that Dey supplied FSS prices to the Department of Veterans Affairs ("VA").[3] Dey's argument that such prices are useful is, at best, a policy debate. The fact remains that FSS prices are determined under a completely separate statutory scheme, and the Medicare and Medicaid programs did not implement systems to use those prices. Dey knew that and took advantage of this for its own private gain. To hold, as Dey urges, that relief in this case is barred because the Medicare and Medicaid programs should have changed the administration of their programs to use FSS prices would enable the kind of "cat and mouse" game that courts eschew. *United States v. Calhoon*, 97 F.3d 518, 529 (11th Cir. 1996).

Dey's arguments ignore the reality of the Medicare Part B and Medicaid reimbursement systems. These programs depend on complex electronic processing systems that require regular input of electronic pricing data to administer millions of claims each month. US-Common-SOF

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[2] 22 Me. Rev. Stat. Annot. § 2698-B (West 2009); 33 Vt Stat. Annot. § 2010 (West 2009); Tex. Admin. Code tit. 1, § 354.1921 (West 2009). The California reporting requirement applies only to companies that have entered into a supplemental rebate agreement with Medi-Cal (9/22/08 Gorospe Dep. at 707:13 - 707:21, Henderson Reply Ex. 64) (which Dey has not done), and, consistent with federal expectations, California has always treated AMP data as confidential. *See* US Reply to Jt Resp. to Common SOF ¶ 100. Dey also omits to mention that the Texas regulation was promulgated specifically to combat false price reporting discovered during the State's AWP litigation and that CMS subsequently told the State of Texas that the data could not be used to calculate reimbursement amounts. Henderson Common Decl. Ex. 31.

[3] *See* 38 U.S.C. § 8126. The FSS drug program is administered by the VA and is described at http://www1.va.gov/oamm/oa/nac/fsss/pharmfsspl_library.cfm.

¶¶ 23-24.[4] The systems have evolved over decades to depend heavily on the compendia for automatic pricing information. The New Jersey Medicaid witness, Edward Vaccaro, illustrated this point when he answered questions about the import of a Dey price notification letter:

> Q. How would the reimbursement system function if you adjusted reimbursement rates each time you received a letter like this?
> A. Chaos.
> Q. Why?
> A. You're processing millions of claims and you have to determine at what point a pricing change impacts the payment of a claim. So you're sensitive to dates of service and from to dates for the pricing change and, of course, we're not going to know the through date for any pricing change because that's not something that's provided to us so it would be impossible to process a claim.

(12/2/08 Vaccaro Dep. at 145:5 - 146:6, Henderson Reply Ex. 16.)

Ironically, at the same time Dey asserts that the government knew about Dey's conduct, Dey appears to dispute virtually every fact that the government alleges about its conduct, including, incredibly, that Dey reported its AWPs and WACs to the compendia, and that Dey knew and expected that those prices would be published. Dey-Opp-SOF ¶¶ 59-60.[5] In addition

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[4] *See also* CMS's Internet-Only claims processing manuals at http://www.cms.hhs.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912. *And see* CMS information on Medicare claims processing systems and data at http://www.cms.hhs.gov/NonIdentifiableDataFiles/06_PhysicianSupplierProcedureSummaryMasterFile.asp.

[5] Dey's purported disputes are not genuine and fly in the face of its unambiguous answer to Interrogatory No. 1 (Henderson-Dey Ex. 19A) and the unambiguous answers of its 30(b)(6) witness, Ms. Pamela Marrs (Henderson-Dey Ex. 21 (Dey 30(b)(6)) at 467:19-467:22), and the Dey employee in charge of price reporting (Henderson-Dey Ex. 10 (12/10/08 Johnston Dep.) at 71:4 - 71:16).

to disingenuous statements about its role in setting the published prices (see US Resp. to Combined SOAF ¶ 149.2), Dey has given highly misleading testimony about its conduct in marketing the spread. US-Dey-SOF ¶¶ 162-166. This is not the sort of full disclosure that can support a "government knowledge" defense as claimed by Dey. The United States' understanding of the nature of Dey's price reporting, its control of the published prices, and its true average sales prices has come only after lengthy investigation and litigation, as Dey acknowledges in its brief (at p. 13).

Dey's price notification letters (Reid Opp. Exs. 30, 109-119) failed to disclose the true facts. First, most of those letters either relate entirely to drugs that are not at issue in this case (Reid Opp. Exs. 109, 110, 112, 115, 117, 118), or provide no AWP price information about the Complaint drugs (Reid Opp. Exs. 30, 109, 113, 114, 116, 119). The letter that Dey quotes in its opening brief (Reid Opp. Ex. 111), provides information about only two of the 26 NDCs alleged in the complaint (and relatively minor ones at that). In short, Dey's disclosure letters state Dey's position about AWP only in connection with two relatively insignificant Complaint Drugs. Moreover, the last letter (Reid Opp. Ex. 119) announces that Dey is *decreasing* its AWPs on two NDCs and *increasing* its AWPs on three NDCs, which is flatly inconsistent with Dey's asserted practice of not changing its AWPs after launch and falsely suggests that Dey's AWPs do indeed reflect real market prices. Nowhere did Dey inform government officials that it had caused the compendia to publish AWPs that were, for example, three to five times higher than its actual average prices in January 2001 (the date of Reid Opp. Ex. 116). *See* Henderson-Dey Ex. 19 (Graphs and Summaries). There is no evidence that Dey has ever informed Medicare and Medicaid officials that the spreads on its drugs have exceeded 1,000 percent since 2004, in the

case of its albuterol sulfate unit dose products, and 1,500 percent in the case of ipratropium bromide.

Importantly, Dey has no evidence that its corporate decision-makers had any awareness of or relied upon the "government knowledge" evidence that Dey presents. Dey effectively concedes that none of its employees who were responsible for the reporting of false prices and marketing the spread ever read any of the various Office of Inspector General ("OIG") reports and other materials relied upon by Dey. US-Dey-SOF ¶¶ 180 - 189, 198. When a Rule 30(b)(6) deposition was taken of Dey concerning the basis for Dey's belief that the government knew about or acquiesced in Dey's price reporting conduct, Dey responded with essentially no evidence other than notebooks of government reports compiled by Dey's litigation counsel for purposes of the deposition. *Id*. ¶¶ 181-183. Dey's Rule 30(b)(6) witness, Pamela Marrs, was unable to identify anybody at Dey who had read any of the reports or relied on them. *Id*. ¶¶ 190-199. When asked who at Dey held the belief that government agencies acquiesced in and/or approved of Dey's conduct, Ms. Marrs identified herself, Dey's former Vice President Robert Mozak, and Dey employee Russell Johnston. *Id*. ¶¶ 191, 194, 195.[6] Ms. Marrs, on behalf of Dey, testified that her own belief was based on communications with counsel, which she declined to reveal. *Id*. ¶ 196. As to Mr. Mozak, Ms. Marrs, on behalf of Dey, was unable to provide any information about the basis of Mr. Mozak's belief. *Id*. ¶ 193. And when Mr. Johnston was subsequently deposed, he testified he had no belief or knowledge on the subject. *Id*. ¶ 197. Dey does not genuinely dispute these facts. Dey Opp. SOF ¶¶ 191-199.

[6] Oddly, Dey says it disputes that Ms. Marrs holds the belief that the government knew and approved of Dey's price reporting practices. *Id.* ¶ 195. See Henderson Common Ex. 61 (Deposition of Dey) at 638:12 - 639:18.

In sum, what the undisputed evidence shows is that during the period when Dey set its AWPs for the subject drugs (1992 through 1997), Dey was unaware of the "government knowledge" evidence that Dey relies on. Yet Dey knew it was reporting inflated AWPs to the compendia for publication; Dey knew that these prices were used to determine reimbursements by Medicare and Medicaid; and Dey knew or should have known that these prices were used to determine providers' "reasonable charges" under Medicare Part B, 42 U.S.C. §§ 1395l(a)(2), 1395x(s), and "estimated acquisition costs" in the Medicaid programs. 52 Fed. Reg. 28648, 28657 (July 31, 1987) (promulgating 42 C.F.R. §§ 447.301, 447.331(b)).

II. ACTIONS BY THE MEDICARE CARRIERS DID NOT BREAK THE CAUSAL CHAIN SET IN MOTION BY DEY'S FALSE PRICING

Dey argues (Dey Opp. Br. at 11-12) that discretion exercised by DMERCs to include or exclude particular NDCs in their arrays is an intervening cause. Having deliberately inflated its reported AWPs and profited from its manipulation of the reimbursement system, Dey is in no position to challenge the DMERCs' application of ministerial discretion in their pricing determinations. That the DMERCs might not establish their pricing arrays with perfection was certainly foreseeable to Dey, and the inflated AWPs reported by Dey undoubtedly were a substantial factor in causing fiscal harm to the Medicare program. *See* Restatement (Second) of Torts § 435(2) (1965) (if an "actor's conduct is a substantial factor in bringing about harm to another, the fact that the actor neither foresaw not should have foreseen the extent of the harm or the manner in which it occurred does not prevent him from being liable"); *Gallick v. Baltimore and Ohio R.R. Co.*, 372 U.S. 108, 120 (1963) ("[A]ssuming the existence of a threshold tort . . .

whatever damages flow from it are recoverable"); *Figueroa-Torres v. Toledo-Davila*, 232 F.3d 270, 275 (1st Cir. 2000) (noting that "an offender 'takes his victim as he finds him.'").

In arguing for a break in the causal chain here, Dey cites to its Response to US-SOF ¶ 205, which observes that, in the 1998 Red Book, Dey's 2.5 ml 30s UD is listed as "PF" or preservative-free (see Henderson-Dey Ex. 97 at p. 7 of 13). Dey argues that, pursuant to the Medicare Claims Processing Manual (which did not exist in 1998), this product therefore should have been excluded from the array. Palmetto included the product in its arrays; CIGNA, on the other hand, excluded it for several quarters, and then included it. Henderson-Dey Ex. 97; Henderson Common Ex. 3 (Helton Decl. at Ex. A). This argument is a red herring because, as Dey knows full well, *all* of the Dey and Roxane ipratropium bromide inhalation solution 0.02% unit dose products listed in the Red Book and the DMERC arrays – including Dey's other products (the packages of 25 and 60) as well as the brand (Atrovent) – were preservative-free.[7] Thus, there was no basis to distinguish Dey's 30s package from any other product on the market, and the mistaken 1998 Red Book "PF" designation was an isolated anomaly. (*See* Henderson-Dey Ex. 97 at p. 10 of 13.)[8] The reasonable decision to include Dey's 30s package along with all

[7] All three of Dey's subject ipratropium bromide products are identical in formulation. (Reid Ex. 9.) The Roxane ipratropium bromide products are identical to the brand product Atrovent, which is preservative-free. *See* Henderson Reply Exs. 96, 97.

[8] In March 1999, shortly before the Red Book anomaly was eliminated, Dey received an inquiry from the Department of Health and Human Services ("HHS") Division of Drug Marketing, Advertising, and Communications (DDMAC) about Dey's misbranding of its ipratropium bromide product. *See* Henderson Reply Ex. 96. The DDMAC subsequently issued a Warning Letter advising Dey that Dey made false and misleading representations that the brand version, Atrovent, contained preservatives that caused side effects. *Id*. In fact, Atrovent did not contain preservatives. *Id*.

the other preservative-free ipratropium products was fully consistent with the objective of the pricing procedure and CMS's interpretation of 42 C.F.R. § 405.517(c). It is nonsense to claim that DMERC "discretion" in including one NDC in these circumstances constitutes an intervening cause.

III. THERE IS NO BASIS TO LIMIT THE TIME FRAME FOR ANY RECOVERY

Dey's claim that due process bars the government's claims after 1997 holds no water.[9] Dey makes no further attempt to show bad faith on the part of the government, *see United States ex rel. Sarmont v. Target Corp.*, 2003 WL 22389119 *6 (N.D. Ill. Oct. 20, 2003), other than to argue that purported prejudice to Dey somehow constitutes a basis for a finding of bad faith. Dey Reply Br. at 15. Dey first claims prejudice in its inability to depose the former medical director at Palmetto (a DMERC), who Dey says was "involved in an OIG investigation relating to fraudulent claims submitted by providers in the Miami area." Of course, investigation of provider fraud in Miami is totally irrelevant to this litigation. Dey does no better with respect to its inability to depose Robert Katz, an HHS OIG employee who Dey says worked on several OIG reports dealing with albuterol. The OIG reports speak for themselves forthrightly, and there is nothing to suggest that a deposition of Mr. Katz might have revealed any relevant non-privileged information that has not been obtained elsewhere. The OIG work papers have been produced (totaling approximately 50,000 pages), and the defendants have deposed seven other HHS OIG personnel over the course of 16 days. A review of Dey's briefs and statements of facts (including joint defense statements of fact) indicates that, if anything from OIG carries significance, it is the

[9] Dey's argument that government knowledge bars claims for albuterol and cromolyn as of 1997, and ipratropium bromide as of 1999, has already been addressed by the United States above and in its Consolidated Memorandum.

OIG reports themselves, not any behind-the-scenes conversations. Dey's recitation of Robert Vito's inability to remember certain details (Dey Reply Br. at 14, citing Dey Ex. 403) illustrates the fallacy of Dey's position. Dey selects a single page of Vito testimony that is devoid of context. A more complete selection of testimony and the related deposition exhibit reveals questioning about a trivial email discussing hotel reservations. Mr. Vito was able to provide substantive testimony about other matters, although none of that testimony has yielded relevant evidence. *See* Henderson Reply Ex. 20 .

If this were a case where Dey met with OIG personnel to disclose Dey's conduct and obtain verbal approval for Dey's practices, and the evidence of such a meeting was lost, Dey might have a better argument. But Dey makes no such claim. To the contrary, Dey concedes it never voluntarily disclosed its conduct to or sought approval from the government, and never relied on any OIG or other government reports in setting its inflated WACs and AWPs. Dey's claim of prejudice should be rejected.

IV. SUMMARY JUDGMENT IS APPROPRIATE AS TO DEY'S 1995 ALBUTEROL WAC REPORTED TO FIRST DATABANK

Dey contends that there are genuine issues of fact concerning Dey's reporting of an inflated WAC to First Databank ("FDB") in May 1997. Dey first argues that a jury could reasonably conclude one Medicaid official (Jerry Wells of Florida) knew and approved of the false WAC and that Dey justifiably relied on that. Putting aside the question whether a communication with one Medicaid official of one state could preclude judgment with respect to other WAC states, the evidence Dey cites simply does not raise a genuine issue. Despite lengthy depositions of Mr. Wells, the totality of the evidence presented by Dey (see Dey-Opp-SOF ¶ 68)

indicates simply that a Dey employee told Mr. Wells that Dey had changed its WAC. There is no evidence that Dey told Mr. Wells what Dey's true wholesale acquisition cost was or that its new reported WAC was highly inflated, and there is not a scintilla of evidence to suggest any approval by Mr. Wells.

There can be no doubt that Dey proximately caused the damages that flowed from its inflated WAC. Even assuming that Dey sent corrected WACs to FDB as Dey claims, FDB's failure to promptly update the prices does not absolve Dey of liability. Dey concedes that it knew that FDB sometimes made mistakes and failed to update price changes as requested. See Dey-Opp-SOF ¶ 68 (last sentence). Having intentionally reported false WACs, it was incumbent upon Dey to ensure that they were corrected, and, by Dey's admission, foreseeable that FDB might not correct them on the first try.

CONCLUSION

For the reasons set forth above and in the plaintiffs' additional summary judgment briefs,

plaintiffs respectfully request that the Court deny Dey's motion for partial summary judgment and grant plaintiffs' motion for partial summary judgment.

Respectfully submitted,

TONY WEST
ASSISTANT ATTORNEY GENERAL

/s/ Laurie A. Oberembt

Joyce R. Branda
Daniel R. Anderson
Laurie A. Oberembt
Civil Division
Commercial Litigation Branch
P. O. Box 261
Ben Franklin Station
Washington, D.C. 20044
(202) 514-3345

MICHAEL K. LOUCKS
ACTING UNITED STATES ATTORNEY

By: /s/ George B. Henderson, II

George B. Henderson, II
Barbara Healy Smith
James J. Fauci
Assistant U.S. Attorneys
United States Courthouse
1 Courthouse Way, Suite 9200
Boston, MA 02210
(617) 748-3272

FOR THE RELATOR,

James J. Breen
Allison Warren Simon
The Breen Law Firm, P.A.
5755 Northpoint Parkway, Suite 260
Alpharetta, GA 30022
Tel. (770) 740-000
fax: (954) 499-1173

Gary Azorsky, Esq.
Susan Schneider Thomas, Esq.
Berger & Montague, P.C.
1622 Locust St.
Philadelphia, PA 19103
(215) 875-3090

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above document to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ George B. Henderson, II
George B. Henderson, II
Assistant U.S. Attorney

Dated: September 22, 2009

Addendum

Abbreviation	Document	ECF Doc. #
Reid Ex.	Exhibits to Declaration of Sarah L. Reid in Support of Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Motion for Partial Summary Judgment	MD #6184 Sub. #240
US-Dey-SOF	United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey	MD #6296 Sub. #302
Henderson-Dey Ex.	Exhibits to Declaration of George B. Henderson, II, Submitting Exhibits in Support of Motion for Partial Summary Judgment [Dey case] (as amended)	MD #6298 Sub. #303 (amended at MD #6331-2, Sub. #336-2)
US-Common-SOF	United States' Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants	MD #6316 Sub. #312
Henderson Common Ex.	Exhibits to Declaration of George B. Henderson, II, Submitting Common Exhibits in Support of Motions for Partial Summary Judgment	MD #6310 Sub. #308
Dey-Opp-SOF	Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Individual Local Rule 56.1 Statement in Opposition to the United States' Local Rule 56.1 Statement of Undisputed Material Facts as to Dey	MD #6432 Sub. #411
Reid Opp. Ex.	Exhibits to Declaration of Sarah L. Reid in Support of Dey's Opposition To Plaintiffs' Motion for Partial Summary Judgment	MD #6426 Sub. #406
Dey Reply Br.	Defendants Dey, Inc., Dey, L.P., and Dey L.P., Inc.'s Reply in Further Support of Their Motion for Partial Summary Judgment and Response to the United States' Cross-motion for Partial Summary Judgment	MD #6445 Sub. #442

Abbreviation	Document	ECF Doc. #
US Resp. to Combined SOAF	United States' Response to Defendants Abbott Laboratories, Inc., Dey, Inc., Dey, L.P., Dey L.P., Inc., and Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc.'s Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent to the United States' Motions for Partial Summary Judgment Against Defendants	[filed 9/22/09]
US Reply to Combined Resp. to Common SOF	United States' Reply to Defendants Abbott, Dey and Roxane's Combined Response to the United States' Statement of Undisputed Material Facts Common to All Defendants	[filed 9/22/09]
Henderson Reply Ex.	Exhibits to Declaration of George B. Henderson, II, Submitting Exhibits in Support of United States' Response to Defendants' Combined Local Rule 56.1 Statement of Additional Material Facts Pertinent to the United States' Motions for Partial Summary Judgment Against Defendants	[filed 9/22/09]